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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,596	02/15/2002	Alan D. Snow	017170-0010-999	2850
20583	7590	12/03/2008		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER CHONG, YONG SOO	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 9/2/2008.

Claims 1-27, 39-54 have been cancelled. Claims 28-38, 55-56 are pending. Claims 28, 36-38, 55-56 have been amended. Claims 28-38, 55-56 are examined herein.

Applicant's new claim amendments have rendered all rejections of the last Office Action moot, therefore hereby withdrawn. The following new rejections will now apply.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28-38, 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Morimoto et al. ("Prenylated Flavan-3-ols and Procyanidins from *Illicium Anisatum*" *Phytochemistry*, 1988, vol. 27, no. 3, pp. 907-910, of record).

Morimoto et al. teaches that *Illicium anisatum* is known to produce shikimic acid, anisatin, essential oils, etc. As a part of chemical studies on tannins and related compounds, the bark of *Illicium anisatum* was investigated. Morimoto et al. report the isolation and structural elucidation of prenylated flavan-3-ols and a new proanthocyanidin from the bark of *Illicium anisatum* (abstract and introduction). On page 909, the structures of compounds 3, 6, and 14 are shown and meet the structural

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limitations of formula I or II in claims 28, 31-38, 55-56, where $n = 2$ or 3 . Furthermore, compound 3 was isolated at 125 mg, compound 6 was isolated at 207 mg, and compound 14 was isolated at 3 mg in ethanol (experimental on page 910).

It is noted that the isolated amounts of compounds 3, 6, and 14 meet the claimed therapeutically effective amount limitations. An average adult rat weighs between 250 to 400 grams, which equates to 2.5 to 400 mg for the therapeutically effective amount of the proanthocyanidin according to claims 29-30.

Furthermore, intended use or preamble will be given little patentable weight since the claims are drawn to a composition. It is respectfully pointed out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish from each other. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Thus, the intended use of a composition claim will be given no patentable weight.

It is further respectfully pointed out that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). See MPEP 2111.02.

Claims 28-38, 55-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al. ("Tannins and Related Compounds. XC. 8-C-Ascorbyl (-)-Epigallocatechin 3-O-Gallate and Novel Dimeric Flavan-3-ols, Oolonghomobisflavans A and B, from Oolong Tea (3)" *Chem. Pharm. Bull.* 1989, vol. 37, no. 12, 3255-3263, of record).

Hashimoto et al. report that the chemical examination of the polyphenolic constituents in commercial oolong tea has led to the isolation of a new flavan-3-ol, two novel dimeric flavan-3-ols, and eight new proanthocyanidins, together with twenty-one known polyphenols including proanthocyanidins, hydrolyzable tannins and red pigments (abstract). On page 3257, compounds 1-11 and on page 3258, compounds 29-32, meet the structural limitations of formula I or II in claims 28, 31-38, 55-56, where $n = 2$. On page 3262, the experimental section reports compound 30 (19 mg) in water (5 ml) and later compound 30 (47 mg) in ethanol. Compound 31 (52 mg) and compound 32 (30 mg) in water (5 ml) are also reported.

Response to Arguments

Applicant argues that Hashimoto does not teach or suggest pharmaceutical compositions because polyphenolic constituents were extracted from oolong tea in 80% aqueous acetone extract. Applicant argues that Morimoto does not teach or suggest pharmaceutical compositions because the bark of *Illicium anisatum* was extracted in 80% acetone. Furthermore, the cited prior art references do not teach or suggest the specific therapeutic amounts or the specific proanthocyanidins claimed in dependent

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claims 29-38, particularly where the proanthocyanidins are dimers and trimers of epicatechin, epiafzelechin, and catechin.

This is not persuasive because the Applicant has clearly misunderstood or misread the cited prior art references. As explained in the rejections above, both Hashimoto and Morimoto teach the isolation of a compound of formula I, where the proanthocyanidin is a dimer or trimer, thus meeting the limitations in claims 31-38 and 56. The proanthocyanidins were isolated and/or purified in water or ethanol, thus forming a pharmaceutical composition. Applicant's arguments concerning acetone only refer to the initial extraction from the bark of *Illicium anisatum* or oolong tea, the original source of the polyphenols. Final purification of the claimed proanthocyanidins of formula I were performed in water or ethanol. Furthermore, the final isolated amounts as disclosed by the cited prior art references meet the specific therapeutic amounts for an average adult rat.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/
Examiner, Art Unit 1617

YSC